

**ADIPEX-P- phentermine hcl 37.5mg tablet**  
**Advanced Rx Pharmacy of Tennessee, LLC**

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**Phentermine HCl 37.5mg tablets #28**

**Dosage and Administration Section**

**2 DOSAGE AND ADMINISTRATION**

**2.1 Exogenous Obesity**

Dosage should be individualized to obtain an adequate response with the lowest effective dose.

The usual adult dose is one tablet (37.5 mg) daily, as prescribed by the physician, administered before breakfast or 1 to 2 hours after breakfast. The dosage may be adjusted to the patient's need. For some patients, half tablet (18.75 mg) daily may be adequate, while in some cases it may be desirable to give half tablets (18.75 mg) two times a day. Phentermine is not recommended for use in pediatric patients  $\leq$  16 years of age.

Late evening medication should be avoided because of the possibility of resulting insomnia.

**2.2 Dosage in Patients With Renal Impairment**

The recommended maximum dosage of phentermine is 15 mg daily for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73m<sup>2</sup>). Avoid use of phentermine in patients with eGFR less than 15 mL/min/1.73m<sup>2</sup> or end-stage renal disease requiring dialysis [see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)].

**Indications and Usage Section**

**1 INDICATIONS AND USAGE**

Phentermine hydrochloride tablets are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index  $\geq$  30 kg/m<sup>2</sup>, or  $\geq$  27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).

Below is a chart of body mass index (BMI) based on various heights and weights.

BMI is calculated by taking the patient's weight, in kilograms (kg), divided by the patient's height, in meters (m), squared. Metric conversions are as follows: pounds  $\div$  2.2 = kg; inches  $\times$  0.0254 = meters.

**BODY MASS INDEX (BMI), kg/m<sup>2</sup>**

**Height (feet, inches)**

**Weight**

**(pounds) 5'0" 5'3" 5'6" 5'9" 6'0" 6'3"**

140 27 25 23 21 19 18

150 29 27 24 22 20 19

160 31 28 26 24 22 20

170 33 30 28 25 23 21

180 35 32 29 27 25 23

190 37 34 31 28 26 24

200 39 36 32 30 27 25

210 41 37 34 31 29 26

220 43 39 36 33 30 28

230 45 41 37 34 31 29

240 47 43 39 36 33 30  
250 49 44 40 37 34 31

The limited usefulness of agents of this class, including phentermine, [see Clinical Pharmacology (12.1, 12.2)] should be measured against possible risk factors inherent in their use such as those described below.

## Principal Display Panel

Each tablet contains:  
37.5 mg of Phentermine HCl, USP  
(equivalent to 30 mg of Phentermine base).

**USUAL DOSAGE:** See package insert  
for complete prescribing information.

Dispense in a tight, light-resistant  
container as defined in the USP with  
a child-resistant closure.


Store at 20° to 25°C (68° to 77°F) [See  
USP Controlled Room Temperature].


**KEEP THIS AND ALL MEDICATION  
OUT OF THE REACH OF CHILDREN.**


This bottle has been sealed for your protection.

NDC 0527-1445-01


# Phentermine HCl Tablets, USP

**37.5 mg** 

 **Only**  
100 Tablets



Distributed by:  
Lannett Company, Inc.  
Philadelphia, PA 19136



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CIB70551C Rev. 11/20

## ADIPEX-P

phentermine hcl 37.5mg tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:80425- 0118(NDC:0527-1445)
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENTERMINE HYDROCHLORIDE</b> (UNII: 0K2I505OTV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE HYDROCHLORIDE	37.5 mg

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	LCI;1445
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0118-1	28 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2005	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040555	04/15/2005	

**Labeler** - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

## Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0118)

Revised: 12/2020

Advanced Rx Pharmacy of Tennessee, LLC